GREGORY J. GLOVER , M.D., J.D.

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FOREIGN COMMERCE AND TOURISM
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U.S. SENATE

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Mr. Chairman and Members of the Subcommittee:

On behalf of the Pharmaceutical Research and Manufacturers of America, I am pleased to appear at this hearing this afternoon on direct-to-consumer (DTC) advertising of prescription medicines. I am a licensed physician and a practicing attorney with the law firm of Ropes & Gray, specializing in FDA regulatory issues and intellectual-property law. PhRMA represents the nation's leading research-based pharmaceutical and biotechnology companies, which are leading the way in the search for new cures and treatments that will enable patients to live longer, healthier, and more productive lives.

This year, PhRMA member companies will invest more than $30 billion to discover and develop new medicines. The mapping of the human genome has opened new frontiers, new paths to better health, pointing the way to treatments never dreamed possible. The industry is most encouraged about the prospects for exponentially better treatments – and, possibly, cures – for Alzheimer's, AIDS, arthritis, cancer, diabetes, heart disease, stroke, and many other diseases.

Just a few weeks ago, for example, a breakthrough drug for leukemia was approved. This medicine, which blocks the biochemical switch that causes normal cells to turn cancerous, heralds a whole new era of very promising cancer research. The FDA is reviewing an application for a new, life-saving drug that reduced the risk of death from sepsis by a dramatic 20 percent in a study published in *The New England Journal of Medicine.* Sepsis kills more than 1,400 people every day and is the leading cause of death in non-coronary intensive-care units with an estimated treatment cost of $17 billion annually in the United States.

Left sitting on the pharmacy shelf, medicines don't do anyone any good. Unless they are prescribed for patients, medicines cannot prolong life, ease pain, reduce disability, or make life better. And unless medicines are prescribed and used, they will not generate the funds needed for private industry to continue to research and develop future cures and treatments.

That is why PhRMA enthusiastically supports DTC advertising of prescription medicines, which is regulated by the FDA, and opposes any further restrictions on this pro-patient, pro-health activity.

Patients are seeking more information as they navigate the increasingly complex maze that is our health-care system. We believe more information is good. Medicines have been proven to be the most cost-effective form of health care and can often keep patients out of hospitals and nursing homes and help them avoid surgery and other, more expensive forms of care. For example, a 1998 study sponsored by the National Institutes of Health (NIH) found that treating stroke patients promptly with a clot-busting drug nets an average savings of $4,400 a year per patient by reducing the need for hospitalization, rehabilitation, and nursing-home care. According to NIH, use of this medicine could save the health-care system more than $100 million a year.

BACKGROUND

Over the course of history, the medical community has resisted DTC advertising of prescription medicines. Physicians wanted tight control over what information was conveyed to patients. In 1555, for example, the Royal College of Physicians in London decreed that "no physician teach people about medicines or even tell them the names of medicines." The fear was that people would use medicines improperly and be harmed.

That attitude persisted for more than 400 years. As recently as the mid-1980s, the FDA imposed a voluntary moratorium on DTC ads. After the moratorium was discontinued, many pharmaceutical companies began advertising their medicines directly to consumers, following FDA rules.

In 1997, the FDA issued guidelines that clarified the agency's broadcast advertising requirements. No longer would the FDA require ads to contain voluminous and often confusing information about a drug's side effects in radio and television ads. Under the FDA's draft guidance, ads must list major health risks as well as side effects, and must set forth four ways for consumers to receive additional information: through an 800 number, an Internet site, reference to a print ad in a major national publication, and through their physician or pharmacist.

The FDA's 1997 decision stemmed from a policy that had led to ineffective and confusing advertisements. Prior to the 1997 guidance, the FDA required that a brief summary of the prescribing information for a drug had to be included in all advertisements that both name a prescription drug and state its purpose, including broadcast ads. The brief summary is an FDA-approved document that advises physicians, in very technical language, how to properly use a drug. Because of technical, scientific wording in the brief summary, it is very difficult for patients and consumers without a medical background to understand.

Prior to the 1997 guidance, pharmaceutical companies that wanted to include both the name of a drug and the condition it was intended to treat were forced to include the small print that constituted this complicated prescribing information. While feasible in newspapers and magazines, such ads were not possible for radio and television. This prompted companies to advertise on television in more oblique ways that, while meeting legal requirements, may not have been very helpful to patients. In such ads, <u>either</u> the name of a medicine <u>or</u> the name of the illness could be mentioned – but not both. Consumers were often left to guess what disease a medicine was intended to treat.

This system was clearly unsatisfactory. As Dr. William Jacott, a trustee of the American Medical Association (AMA), said at the time: "The problem with the way the FDA currently regulates ads is that they discourage companies from providing information that may educate the consumer. The merest mention of symptoms and a drug requires that a company also include reams of information that most people won't read and many wouldn't understand anyway."

In announcing the clarifying guidance in August 1997, Michael Friedman, M.D., then FDA Lead Deputy Commissioner, said: "Today's action can help promote greater consumer awareness of prescription drugs." And Robert Temple M.D., Associate Director for Medical Policy at the FDA's Drug Division, said that, under the new guidance, ads could inform consumers about new products about which they might not otherwise learn. As an example, he cited a new generation of antihistamines that don't cause drowsiness. "You need to be told by someone that those products are out there or you'll never know," he said.

THE INFORMATION REVOLUTION IN HEALTH CARE

Under current practices, patients now are more actively involved in their own health destinies than ever before. The consumer movement and the information explosion have empowered patients to participate in decisions concerning their health care. Armed with information, patients have become

active partners with health-care professionals in managing their own health care. And they are savvy consumers.

Rather than remaining uninformed and relying entirely on an increasingly complex health-care system, patients are asking questions, evaluating information, and making choices. Direct-to-consumer advertising provides a valuable resource for patients to obtain information about specific diseases, conditions, and treatments, particularly in rural areas of the country where access to providers and health-care information may be difficult.

Too often, many common yet serious conditions go untreated even though effective treatments are available. Affected individuals may not realize that they need treatment. Others who are aware of their symptoms may not know that treatment is available. Patients suffering from chronic conditions may be dissatisfied with their current treatment, but may be unaware that different options are available with fewer side effects or an easier dosing regimen.

Advertising, however, is only one source of user-friendly information that consumers have at their disposal. Some 50 consumer magazines focusing on health care reach the news stands every month. Just about every television station in the country has an on-screen physician.

The *Physician's Desk Reference*, or *PDR*, once confined to doctors' offices, is now available in a consumer edition at pharmacy counters. Internet users can surf tens of thousands of sites dedicated to health-care topics. In fact, according to health-care consultant Lyn Siegel, about 25 percent of online information is related to health care and more than half of the adults who go on the web use it for health information. So, while DTC advertising is an important source of information for consumers, it is clearly not their only source. But DTC advertising is the most accurate because it is regulated by the FDA.

DTC advertising helps to meet the increased demands of consumers for information about diseases and treatments. Most important, DTC advertising can improve public health. It is intended to start a dialogue between patients and doctors. Often, this dialogue will not result in a doctor prescribing the drug mentioned by a patient. But it will prompt a discussion that may lead to better understanding and treatment of a patient's condition. It should be emphasized, however, that physicians ultimately decide whether therapy is needed, and, if so, which therapy is most appropriate for a particular patient.

UNDERDIAGNOSIS AND UNDERTREATMENT

Pharmaceutical advertisements raise awareness of conditions and diseases that often go undiagnosed and untreated. For example, the American Diabetes Association estimates that six million Americans have diabetes but don't know it. One third of the people with major depression seek no treatment and millions of Americans are unaware that they have high blood pressure. By informing people about the symptoms of such diseases and the availability of effective, non-invasive treatments, DTC advertising can improve public health.

There are encouraging signs that this is happening. Following are just a few examples:

- **A survey by *Prevention Magazine* found that, as a result of DTC advertising, an estimated 24.7 million Americans talked to their doctors about a medical condition they had never discussed with a physician before. In other words, millions of people who had previously suffered in silence were encouraged to seek help.**

- **A 1999 survey by the FDA found that 27 percent of respondents asked their doctors about a condition they had not discussed before. Conditions ranged from diabetes and heart disease to arthritis, depression, and other under-treated conditions.**

- **In the two years that ads for a medicine for erectile dysfunction have appeared, millions of men have visited their doctors to request a prescription for the drug. For every million men who asked for the medicine, it was discovered that an estimated 30,000 had untreated diabetes; 140,000 had untreated high blood pressure, and 50,000 had untreated heart disease. These numbers are striking — and they're just for one drug.**

- **A study by IMS Health, a health-care information company, found that, in the one year after an advertising campaign for an osteoporosis drug began, physician visits by women concerned about this disease doubled.**

- **According to a survey by Scott-Levin, a consulting firm, the number of patients visiting their physicians for treatment of depression has increased from about 17 million in 1996, before treatments for depression were widely advertised to consumers, to more than 20 million last year.**

- **Some 19 million Americans have moderate to severe disability from migraines, and 11 million of them are untreated or are treated sub-optimally. Migraine sufferers miss more than 157 million workdays a year and cost U.S. employers as much as $17 billion annually in decreased productivity. The good news is that, since migraine medicines began to be advertised to consumers, the**

number of people who visited their physicians for treatment rose from about 6,200,000 in 1996 to about 7,100,000 last year, according to a study by Scott-Levin.

- **Many health-care organizations reported an increase in requests for information since DTC advertising restrictions were eased in 1997. For example, the American Foundation for Urological Disease experienced a 30- 40 percent increase in requests for information.**

SPILLOVER BENEFITS

According to a recent analysis of consumer surveys by John E. Calfee, Ph.D., of the American Enterprise Institute, DTC advertising also provides important "spillover" benefits to patients, which have nothing to do with the specific products advertised.

One such benefit is an increased awareness that virtually all prescription medicines have risks and side effects. In addition, physicians, when discussing conditions highlighted in advertising such as obesity and high cholesterol, are able to suggest lifestyle changes to their patients. And DTC advertising also improves compliance – it prompts patients actually to take their prescribed medicines. In response to a *Prevention* survey question, 31 percent of the respondents said that ads made them "more likely" to take their medicines regularly, compared to only 2 percent who said they were "less likely" to do so.

According to Express Scripts Senior Director of Outcomes Research, Brenda Motheral, Ph.D., who was quoted in the *Pink Sheet* on March 5, 2001: "People are sticking with their chronic medications in higher proportions than what we've seen in the past… Probably a big driver of that, based on some work that our group has done, is direct-to-consumer advertising."

THE VIEWS OF CONSUMERS, PHYSICIANS, AND REGULATORS

A growing body of evidence suggests that consumers like DTC advertising. A 1999 survey by the FDA found that those who liked these ads outnumbered those who did not by nearly 2 to 1. Eighty-six percent said the ads "help make me aware of new drugs," and 62 percent said the ads helped them have better discussions with their physician about their health. A survey by *Prevention Magazine* found that 76 percent of respondents thought the ads "help people be more involved in their health care" and 72 percent felt the ads "educate people about the risks and benefits of prescription medicines."

The best way to understand how patients feel about DTC advertising is simply to listen to them. Following are comments from patients written to PhRMA companies:

A patient with herpes wrote: "For many years people have suffered in silence and shame. Making it known that this product is available helps those in need. Putting advertisements in magazines and television was a wonderful idea."

A patient with chronic obstructive pulmonary disease (COPD) stated: "You have a commercial on TV that mentions COPD and educates the public – in about 30 seconds – as to the prevalence of the disease. I firmly believe more public education is not just useful but necessary as the number of people with COPD increases. So I want to thank you for raising public awareness of this dreadful disease, and also I want to say thanks for helping to keep me alive these past ten wonderful years."

Finally, a patient with asthma wrote: "My concern is the fact that this product is not being advertised enough. I have cut back my asthma episodes by 80-90 percent. I have had asthma since I was 3 years old and am now 51. Please get the word out about how well this product works."

There also is growing acceptance of DTC advertising by doctors. Historically, physician organizations, as well as individual physicians, have expressed concerns about DTC advertising. However, a 2000 survey by Louis Harris Interactives and the Harvard University School of Public Health found that 64 percent of doctors believe that DTC advertising of prescription drugs helped "educate and inform" their patients, and 40 percent of the doctors surveyed believe the ads increased patient compliance.

A 1999 survey by the FDA showed that, when patients asked physicians about an advertised medicine, 81 percent of patients said the doctor welcomed the question. Only 4 percent said their physicians appeared angry or upset when asked about a medicine. According to *Prevention,* only 26 percent of patients who talked to their physicians about an advertised medicine actually asked for a prescription, while 72 percent asked for more information.

The AMA continues its support of accurate pharmaceutical advertising as "appropriate and legal," according to a letter by Dr. Richard Johnson in the July 6 issue of the *Bergen Record.* Writing to clarify recent reports about AMA's policy on DTC advertising, Dr. Johnson, who heads the Association's relevant Reference Committee, stated that the Committee provided language to the AMA House of Delegates "from numerous physicians who testified that DTC ads are valuable because they sometimes educate consumers about health conditions and

possible treatments that inform consumers better. Testimony also indicated that drug ads may encourage some patients to seek out their physicians and have more knowledgeable discussions about their health conditions and, if applicable, treatment options."

The FDA, reaffirming in August 1999 its policy of permitting DTC advertising, stated: "FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising."

INCREASED DRUG UTILIZATION: A POSITVE DEVELOPMENT

Critics of DTC advertising claim that it drives up pharmaceutical expenditures. While total pharmaceutical expenditures are rising because there is a growing realization of the value of prescription medicines, drug expenditures still make up less than 10 cents of every health-care dollar.

The fact that more patients are getting more and better medicines is good news – for patients, for the health-care system, and for society. Just a few weeks ago, the federal government published new cholesterol standards in an urgent attempt to encourage people to reduce their risk of heart attacks. The National Institutes of Health recommended that millions more Americans should take cholesterol-lowering drugs, which would nearly triple the number of adults using these drugs. Dr. Claude Lenfant, director of the Heart Institute, said that adherence to these guidelines could mean that heart disease would no longer be the top killer of Americans.

Following are a few more examples of the cost-effectiveness of medicines, using drugs that have been the subject of DTC advertising:

- **A cholesterol-lowering drug was found to reduce hospital admissions by a third during five years of treatment, according to a study by University of Pennsylvania researchers. In addition, patients who were admitted to hospitals had shorter stays and were less likely to need bypass surgery or angioplasty. Said Dr. Sanford Schwartz, a physician and economist at the University of Pennsylvania: "This is both good medicine and good economics."**

- **A study published in *The Journal of the American Medical Association* showed that treating Type 2 diabetes with a medicine to improve glycemic control improved the quality of life for patients and helped keep them out of the hospital and on the job.**

- **A study published in *Health Economics* found that medical costs declined by $822 per employee per year and absenteeism dropped by nine days when depressed workers were treated with prescription medicines. Savings from improved productivity and the reduction in work loss and medical costs far outweighed the cost of the treatment.**

ADVERTISING PROMOTES COMPETITION

People often confuse total drug expenditures, which are going up for the public-health reasons just outlined, and drug-price increases, which have been in line with inflation in recent years. According to IMS Health, total drug expenditures rose 14.7 percent in 2000. Of that figure, only 3.9 percent represented price increases. The remaining 10.8 percent reflects utilization—the fact that more patients are using newer and more effective medicines.

The increased use of prescription drugs is a healthy trend. Drugs not only save lives – they save money in many cases by reducing the need for alternative, more expensive care such as hospitalization, confinement in a nursing home, and surgery. Still, only 8.2 percent of every health-care dollar is spent on prescription medicines, compared to 32 percent on hospital care and 22 percent on physician and clinical services.

Historically, advertising has promoted competition and increased volume of sales. If anything, this tends to lead to lower – not higher – prices.

CONCLUSION

In summary, DTC advertising helps to meet the increased demands of consumers for information about diseases and treatments. More important, however, DTC advertising can improve public health. It is intended to start a dialogue between patients and doctors that may lead to a better understanding and treatment of a patient's condition.

Mr. Chairman and Members of the Subcommittee, I hope that you will support patients and oppose those who advocate adoption of a "don't tell, don't ask" public-health policy: don't tell people about new medicines – and hope they won't ask. That policy would be detrimental to public health.

Instead, I hope you will stand behind the patients' right to know about new medicines, to seek information from a variety of sources, including DTC advertising, and to work with their physicians to help themselves to better health. Ultimately, a physician determines the appropriate medical treatment and may or

may not prescribe a medication that may or may not have been advertised and mentioned by a patient.

Thank you very much. I would be happy to answer any questions.